DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

FulLife Natural Options, Inc.
4756 Boca Raton BLVD
Suite 3
Boca Raton, FL 33431

Dear Sir or Madam:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.charanteausa.com and has determined that the product Charantea is promoted for conditions that cause the product to be a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web site establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

Examples of some of the claims observed on your web site in the form of testimonials include:

- "It . . . reduces blood sugar levels, balances insulin level, …."
- "Charantea helps me lower my blood sugar level naturally."
- "With Charantia fortifying my diet, my doctor is able to reduce my medication."
- "I am a diabetic for 15 years now. . . . The combination of insulin and this tea allows me to gain better control of my diabetes."

Other claims found on your web site:

- "In many cases, . . . they were able to greatly reduce the more expensive diabetes medicines."
- "The addition of Charnatea food supplements helps sensitize the body to the diabetic medications."
- "It is also our experience that in most cases, after a few days or within a month after our diabetic patients starts drinking Charantia tea to fortify their usual daily diet, regular exercise and medication, their blood sugar goes down to an even lower level than before, there is less sharp rises [sic] or 'spiking' and it remains more stable for longer periods of time."
- "What I've seen in my patients is that their blood sugar has decreased, plus they felt much better and those who have wounds, they healed faster (with regular use of Charantia)."

These claims are further supplemented by the metatags that you use to bring consumers to your website. These metatags include "Enjoy Lower Blood Sugar Naturally," and "Proven to improve glucose tolerance & lower blood sugar."

Furthermore, your product is not generally recognized as safe and effective for the above referenced conditions and therefore, the product is also a "new drug" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. Your product "Charantea" is also misbranded within the meaning of section 502(f)(1) of the Act, in that the labeling for this drug fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

This letter is not intended to be an all-inclusive review of your web site and products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. We urge you to review your web site, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act.

Failure to promptly correct the violations specified above may result in enforcement action without further notice. Enforcement action may include seizure of violative products and/or injunction against the manufacturers and distributors of violative products.

Please advise this office in writing, within 15 working days of receipt of this letter, as to the specific steps you have taken or will be taking to correct these violations, including the steps taken to assure that similar violations do not recur. Include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Your reply should be addressed to Kristen Moe, Compliance Officer, Food and Drug Administration, Division of Compliance and Enforcement, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835. If you prefer to respond electronically, send your e-mail to kristen.moe1@FDA.HHS.GOV. If you have any questions concerning this letter, please contact Ms. Moe at 301-436-2064.

Sincerely,

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition